

REMARKS

Amendments

Applicants have amended independent claim 1 to recite a porous silk fibroin material having a mean pore size of at least 225 microns. Support for this amendment is found at page 9, paragraph [0173], lines 11-12 and Figures 16J-16L, which describe and show scaffolds prepared using the Applicants method, having mean pore sizes of 225 microns and 425 microns. Applicants have cancelled claim 2. Amendments have been made to the specification to correct typographical errors. Applicants submit that no new matter has been added by way of these amendments.

Formalities

Applicants would like to bring to the Examiners attention that Claims 10 and 11, while rejected, were not addressed in the Office Action mailed on July 10, 2009.

Information Disclosure Statement

Applicants thank the Examiner for providing a PTO-892 to disclose WO-01/154667 and WO-01/80921. Applicants have reviewed Private PAIR and respectfully submit that all foreign and non-patent references listed on the Form 1449 are in the electronic file wrapper of PAIR.

Applicants respectfully request that the Examiner reconsider the information disclosure filed on January 27, 2006 and make the references of record. If there is still an issue, Applicants request that the Examiner informs the Applicant of the same.

Objection to Specification

The Examiner has objected to line 1 of the amendment filed 30 June 2005. Applicants submit that they have amended the paragraph cross reference to related Applications to recite the serial number of the instant application i.e., 10/541,182.

The Examiner has objected to the term “*Bombyx Mori*” in the Amendment filed on June 14, 2006. Applicants respectfully submit that they have amended the Specification at paragraphs 0118 and 0142 to recite “*Bombyx mori*” rather than “*Bombyx Mori*.”

Applicants respectfully request withdrawal of the objection to Specification.

Claims 1-8 have been rejected under 35 U.S.C. 102(b) as being anticipated by Tsukada et al. (1994, Preparation and Application of Porous Silk Fibroin Materials, J. Applied Polymer Science, 54: 507-514).

The Applicants amended claims are directed to a porous silk fibroin material comprising a three-dimensional silk fibroin body having interconnected pores, wherein the mean pore size of the silk fibroin body is at least 225 microns and, wherein the material has a compressive modulus of at least 100 kPa. Applicants respectfully submit that Tsukada et al. does not teach silk fibroin materials having a mean pore size of at least 225 microns, and thus does anticipate the Applicant's claimed invention. The mean pore diameter size discussed in Tsukada et al. ranges from 2.5 microns to 106 microns (Figures 5 and Table 1). As such, there is no anticipation that the rejection should be withdrawn.

Claims 1-9 have been rejected under 35 U.S.C. 103(a) as being obvious combined teachings from Tsukada et al. in view of Li et al., (2002 Study on Porous Fibroin Materials; 3. Influence of Repeated Freeze-Thawing of the Structure and Properties of Porous Silk Fibroin Materials, Polymer Adv. Technology, Vol. 13, 605-610) and Alcock et al. (U.S. Patent 5,736,188) and further in view of Elçin et al. (1996. Controlled release of endothelial cell growth factor from chitosan-albumin microspheres for localized angiogenesis: in vivo studies, Artificial Cells Blood Substitutes and Immobilization Biotechnology 1996 May; Vol. 14, (3), 257-71).

The Applicants have identified a method that enables the generation of a silk fibroin scaffold having mean pore sizes greater than those that have ever been produced previously using standard art methods for production of silk scaffolds (see figures 16k and 16L). The method involves the preparation of an aqueous silk fibroin solution followed by freeze drying to produce a silk foam that is then dissolved in a solvent to make a highly viscous silk (e.g. 17%) solution. The viscous solution is then be processed by salt leaching or gas foaming (see figure 1).

Applicants respectfully submit that, as set forth above, Tsukada does not teach or suggest a porous silk fibroin material having a mean pore size of at least 225 microns, as currently claimed. The secondary references, Li et al., Alcock et al., or Elçin et al. do not make up this deficiency. Li et al, teaches increasing the average pore size from 67 μ m to 120 μ m. There is no teaching to go beyond 120 μ m nor how to accomplish such a result.

Even if one was to combine or modify the teaching of Tsukada et al as suggested by the Examiner, without the benefit of Applicants' teaching, which was not in the art, production of pores silk fibroin materials having the claimed characteristics would not result.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-9 under 35 U.S.C. 103(a).

Should any fee deficiencies be associated with this submission, the Commissioner is authorized to debit such deficiencies to the Nixon Peabody Deposit Account No. 50-0850. Any overpayments should be credited to said Deposit Account.

Respectfully submitted,

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